REPUBLIC OF LITHUANIA

LAW

ON ETHICS OF BIOMEDICAL RESEARCH

11 May 2000 No VIII-1679

Vilnius

(As last amended on 15 November 2007 – No X-1325)

CHAPTER ONE
GENERAL PROVISIONS

Article 1. Scope of this Law

Version of paragraph 1 before 1 January 2008:

1. This Law shall set forth requirements for and principles of the ethics of biomedical research, a procedure for granting authorisations to conduct biomedical research, a procedure for controlling the conducting of biomedical research and liability for violation of requirements of this Law.

Version of paragraph 1 after 1 January 2008:

1. This Law shall set forth requirements for and principles of the ethics of biomedical research, a procedure for granting authorisations to conduct biomedical research, a procedure for controlling the conducting of biomedical research and liability for violation of requirements of this Law. Requirements for clinical tests of a medicinal product shall be set forth, in addition to this Law, by the Republic of Lithuania Law on Pharmacy and other legal acts.

2. Biomedical research must be conducted according to the principle that the interests of the human being prevail over the interests of society and science.

Article 2. Definitions

1. **Biomedical research** means verification of hypotheses of biomedicine by methods of scientific research and development of knowledge about characteristics of human health.

Version of paragraph 2 before 1 January 2008:

2. **Sponsor of biomedical research** means a natural or legal person which initiates, finances, supervises and is responsible for conducting of biomedical research, consequences thereof and publication of research findings.

Version of paragraph 2 after 1 January 2008:

2. **Sponsor of biomedical research** means a natural or a legal person or a branch of an enterprise established in a Member State of the European Union or another state of the European Economic Area which is registered in the Republic of Lithuania and which initiates, finances, supervises biomedical research and takes responsibility for its conduct, consequences and publication of the research findings.

3. **Ethics of biomedical research** means adherence to the ethical requirements and principles as provided for in this Law when conducting biomedical research.

4. **Embryo** means the stage of development of a human organism from the moment of impregnation (formation of a zygote) until the end of the eighth week of a woman's pregnancy.

Version of paragraphs 5-18 before 1 January 2008:

5. **Confidentiality of information** means preservation of information about the subject's state of health, diagnosis, prognosis, medical treatment and other personal data relating to the subject's health.

6. **Informed consent** (hereinafter referred to as a "**consent**") means an explicit and knowing written consent by the subject to participate in a biomedical research.

7. **Clinical research** means biomedical research in human subjects.

8. **Clinical trial of a medicinal product** means any biomedical research in human subjects intended to discover, verify and confirm the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study absorption, distribution, metabolism and excretion of one or

more investigational medicinal product(s) with the object of ascertaining the safety and/or efficacy of an investigational medicinal product.

9. **Authorisation** means an authorisation granted by the Lithuanian Bioethics Committee or the Regional Biomedical Research Ethics Committee to conduct a biomedical research.

10. **Non-clinical research** means the research not involving human subjects.

11. **Subject** means a person who participates in a biomedical research.

12. **Representative of the subject** means a legal representative or an appointed representative. The authorisation of the appointed representative must be executed in accordance with the procedure laid down by laws of the Republic of Lithuania.

13. **Investigator** means a doctor or a person who may conduct a biomedical research because of an appropriate education and the experience in patient care. The investigator shall be responsible for the conduct of a biomedical research at a research site. Where the investigator himself conducts a biomedical research or leads a team of individuals conducting a research at the research site and is responsible for the activities of this team, he may be called the principal investigator. Qualification requirements for the principal investigator shall be set forth by the Ministry of Health.

14. **Foetus** means the stage of development of a human organism from the ninth week of a woman's pregnancy until birth.

15. **Human embryo's stem cells** means the cells of a human embryo which can divide *in vitro* and/or can develop into specialised types of cells.

16. **Human embryo's stem cell line** means the stem cells of an embryo which can be grown *in vitro* and divide without differentiating into other types of cells for a long period of time.

17. **Human stem cells** means the unspecialised cells present during the period of development of an embryo and foetus as well as in tissues of an adult person which are capable to differentiating into specialised cells of different tissue types and renew at the same time.

18. **Human stem cell line** means the human stem cells which are grown *in vitro* ensuring their long-term division without differentiation.

The Article shall be supplemented with paragraph 5; paragraphs 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17 and 18 shall be renumbered as paragraphs 6, 7, 8, 9, 10,

11, 12, 13, 14, 15, 16, 17, 18 and 19 respectively, paragraph 9 shall be amended, and paragraph 10 shall be repealed as of 1 January 2008:

5. **Ethical supervision** means the activities carried out by the Lithuanian Bioethics Committee or the Regional Biomedical Research Ethics Committee and having the purpose of controlling compliance of natural or legal persons with requirements and principles of ethics of biomedical research in conducting biomedical research.

6. **Confidentiality of information** means preservation of information about the state of health of the research subject, diagnosis, prognosis, medical treatment and other personal data relating to the subject's health.

7. **Informed consent** (hereinafter referred to as a "**consent**") means an explicit and knowing written consent by the subject to participate in a biomedical research.

8. **Clinical research** means biomedical research in human subjects.

9. **Clinical trial of a medicinal product** means any biomedical research in human subjects intended to discover, verify and confirm the clinical, pharmacological and/or other pharmacodynamic effects of one or more investigational medicinal product(s), and/or to identify any adverse reactions to one or more investigational medicinal product(s) and/or to study resorption, distribution, metabolism and excretion of one or more investigational medicinal product(s) with the object of ascertaining the safety and/or efficacy of an investigational medicinal product.

10. (Repealed on 1 January 2008).

11. **Non-clinical research** means the research not involving human subjects.

12. **Subject** means a person who participates in a biomedical research.

13. **Representative of the subject** means a legal representative or an appointed representative. The authorisation of the appointed representative must be executed in accordance with the procedure laid down by laws of the Republic of Lithuania.

14. **Investigator** means a doctor or a person who may conduct a biomedical research because of an appropriate education and the experience in patient care. The investigator shall be responsible for the conduct of a biomedical research at a research site. Where the investigator himself conducts a biomedical research or leads a team of individuals conducting a research at the research site and is responsible for the activities of this team, he may be called the principal investigator. Qualification requirements for the principal investigator shall be set forth by the Ministry of Health.

15. **Foetus** means the stage of development of a human organism from the ninth week of a woman's pregnancy until birth.

16. **Human embryo's stem cells** means the cells of a human embryo which can divide *in vitro* and/or can develop into specialised types of cells.

17. **Human embryo's stem cell line** means the stem cells of an embryo which can be grown *in vitro* and divide without differentiating into other types of cells for a long period of time.

18. **Human stem cells** means the unspecialised cells present during the period of development of an embryo and foetus as well as in tissues of an adult person which are capable to differentiating into specialised cells of different tissue types and renew at the same time.

19. **Human stem cell line** means the human stem cells which are grown *in vitro* ensuring their long-term division without differentiation.

Article 3. Objectives, Objects and Peculiarities of Conducting Biomedical Research

1. Biomedical research may be undertaken on human subjects or their groups, a foetus, tissues, organs, cells and genetic material, cadavers and medical documents. Human subjects or their groups and a foetus may undergo biomedical research only where comprehensive data about relevant non-clinical trials are available. Non-clinical trials must be conducted in conformity with the Guidelines for Good Laboratory Practice approved by the Ministry of Health. Clinical trials must be conducted in accordance with the Guidelines for Good Clinical Practice approved by the Ministry of Health.

2. Human embryos may be subjects only of clinical observations (non-interventional trials). Other biomedical research involving human embryos, also their creation for the purposes of biomedical research shall be prohibited. A foetus may be subject only of such biomedical research where the potential benefit to the foetus under investigation exceeds medical risks.

3. Import into the territory of the Republic of Lithuania and export therefrom of tissues of a human embryo, stem cells of an embryo and lines thereof or tissues of a foetus and the stem cells taken therefrom and lines thereof shall be prohibited. This prohibition shall not apply to the import into the territory of the Republic of Lithuania and export therefrom of the stem cells taken from umbilical cord or placenta after the birth of a child and the samples taken for genetic research in accordance with requirements of paragraph 2 of this Article. Transit through the territory of the Republic of Lithuania of tissues of a human embryo, stem cells of an embryo and lines thereof or tissues of a foetus and the

stem cells taken therefrom and lines thereof shall be possible only subject to authorisation by the Ministry of Health. A Description of the Procedure for Authorising the Transit Through the Territory of the Republic of Lithuania of Tissues of Human Embryos, Stem Cells of an Embryo and Lines Thereof or Tissues of a Foetus and the Stem Cells Taken Therefrom and Lines Thereof as well as a Description of the Procedure for Importing into the Territory of the Republic of Lithuania and Exporting Therefrom of the Stem Cells Taken from the Umbilical Cord or Placenta after the Birth of a Child and the Samples Taken for Genetic Research shall be specified by the Minister of Health.

4. Cloning of a human being shall be prohibited.

5. The peculiarities of the biomedical research undertaken on cadavers and medical documents shall be specified by laws and by the Lithuanian Bioethics Committee.

CHAPTER TWO
REQUIREMENTS FOR ETHICS OF BIOMEDICAL RESEARCH

Article 4. Requirements for Ethics of Biomedical Research

Biomedical research may only be conducted if the following requirements are met:

1) biomedical research has scientific and practical merit;

2) protection of interests of the subject and confidentiality of information about the subject has been ensured;

3) free consent of the subject has been obtained;

4) the investigator and the sponsor of biomedical research are covered by the third-party insurance against possible damage to the subject;

Version of subparagraph 5 before 1 January 2008:

5) an authorisation of the Lithuanian Bioethics Committee or a Regional Biomedical Research Ethics Committee has been obtained;

Version of subparagraph 5 after 1 January 2008:

5) the documents of the institutions indicated in Article 12 of this Law granting the right to conduct a biomedical research have been obtained;

6) there are no prohibitions against it in other laws.

Article 5. Vulnerable Subjects

1. Vulnerable subjects shall be the persons whose consent to participate in biomedical research may be influenced by external circumstances. The following subjects shall be regarded as vulnerable:

1) persons with mental disorders, but capable of giving their consent to participate in biomedical research;

2) minors;

3) students, where their participation in biomedical research is related to their studies;

4) persons in nursing homes;

5) soldiers in the active military service;

6) personnel of health care institutions where biomedical research is being conducted who are subordinate to the investigator.

2. Biomedical research may not be undertaken on persons kept in prisons or other imprisonment institutions.

3. Other groups of persons may be recognised as (attributed to) vulnerable subjects by a reasoned decision of the Lithuanian Bioethics Committee.

4. Vulnerable subjects shall be applied additional measures for the protection of their interests specified in Article 7 of this Law.

Article 6. Protection of Interests of the Subject

With a view to protecting the interests of the subject, biomedical research shall be undertaken only where:

1) biomedical research may not be replaced by any another research without the involvement of human subjects;

2) free consent of the person has been obtained;

3) the person who does not give his consent to participate in biomedical research or who withdraws his consent shall not be deprived of his right to be provided with an appropriate health care;

4) the risks that may be incurred by the research subject must not be disproportionate to the potential benefits he derives from participation in the research. As a rule, the expected treatment may not be administered to the subject only when its efficacy has not been proved or when its non-administration does not pose a risk to the health of the subject;

5) the principal investigator and the sponsor of biomedical research are covered by the third-party insurance for compensation of the damage caused to the subject's health and the fatal damage incurred by biomedical research.

Article 7. Protection of Interests of Vulnerable Subjects

1. Biomedical research involving vulnerable subjects shall be permitted only where:

1) such biomedical research may be undertaken only on vulnerable subjects;

2) the results of the biomedical research may be of direct and real benefit to the health of these subjects;

3) the biomedical research will not pose a risk to the health or life of the subject.

2. If the subject is a minor, consent to undertake a biomedical research shall be given by both parents or legal representatives of the minor and the children's rights protection agency of a district or a city. Where the parents of a minor are separated, consent of one of the parents or of the legal representative and of the children's rights protection agency of the district or the city must be obtained.

3. The consent of a psychiatric patient capable of giving knowing consent to take part in a biomedical research must be attested by two witnesses and the head of a health care establishment where the biomedical research is being conducted. Approval of the Medical Ethics Commission must also be obtained. The procedure for forming the Medical Ethics Commission and conducting its activities shall be laid down in the Model Regulations of the Medical Ethics Commission of a Health Care Establishment approved by the Ministry of Health.

Article 8. Consent

1. Biomedical research shall be undertaken after the subject has given his written consent. Before giving his consent, the subject shall be provided, against signature, with information understandable to him about the goal, plan of the research and the methods applied, decisions of the Lithuanian Bioethics Committee or an appropriate Regional Biomedical Research Ethics Committee as well as about the following:

1) foreseeable benefits of the biomedical research to the subject;

2) the rights, foreseeable risks and inconveniences which the biomedical research may cause to the subject as well as the compensation available to the subject in the event of the damage incurred by the biomedical research;

3) the right of the subject to revoke his consent to participate in the biomedical research in writing at any time, providing to him information about the consequences of such discontinuation of the biomedical research;

4) guarantees of confidentiality of the information.

2. A decision on whether the consent is necessary for conducting biomedical research on tissues, organs, a foetus, cell or genetic material which had been obtained from a person for other purposes during medical interventions before applying for undertaking research on this person, also when biomedical research is undertaken on medical documents shall be taken by the Lithuanian Bioethics Committee or a Regional Biomedical Research Ethics Committee granting an authorisation.

Article 9. Confidentiality of Information

1. Information obtained in the course of a biomedical research about the subject's state of health, diagnosis, prognosis, medical treatment and other health-related personal information shall be confidential and may be provided only in accordance with the procedure laid down by the Law on the Rights of Patients and Compensation of the Damage to Their Health.

2. The information obtained in the course of biomedical research about the subject's state of health, diagnosis, prognosis, medical treatment and other health-related personal information shall not be regarded as confidential and may be made public without the subject's consent if the subject's identity remains undisclosed after such information is made public.

Article 10. Reimbursement of Expenses

Subjects shall be entitled to reimbursement of expenses for participating in a biomedical research. The procedure for calculating and paying these expenses shall be laid down by the Government or an institution authorised by it.

Article 11. Third-Party Liability of the Sponsor of Biomedical Research and the Principal Investigator and Its Insurance

1. The sponsor and the investigator of biomedical research shall be liable for the damage resulting from injury to the health of the subject or the death of the subject as well as for the non-pecuniary damage incurred by the biomedical research where they fail to prove that the damage has resulted from causes unrelated to the biomedical research or

from deliberate acts of the subject. The damage done to health by the sponsor of biomedical research and the investigator, the damage incurred by reason of death and the non-pecuniary damage resulting therefrom shall be redressed in the cases specified in the Law on the Rights of Patients and Compensation of the Damage to Their Health and in accordance with the procedure laid down by the Civil Code.

2. The sponsor and the principal investigator of biomedical research must be covered by the third-party insurance against the damage which could be incurred to the subject during a biomedical research under Compulsory Third-Party Insurance Contracts of the Principal Investigator and the Sponsor of Biomedical Research concluded with insurance companies having an authorisation of the State Insurance Supervisory Authority at the Ministry of Finance to provide this type of insurance. This requirement shall apply only where biomedical research is undertaken on human subjects.

3. The Rules of Compulsory Third-Party Insurance of Principal Investigators and Sponsors of Medical Research laying down the procedure for calculating the extent of damage to the subject's health and compensating for it shall be approved by the Government or an institution authorised by it.

CHAPTER THREE
PROCEDURE FOR CONTROLLING THE CONDUCT OF BIOMEDICAL RESEARCH

Version of Article 12 before 1January 2008:

Article 12. Institutions Granting Authorisations

1. Biomedical research may be performed in Lithuania only subject to obtaining of an authorisation of the institutions referred to in paragraph 2 of this Article. Conduct of biomedical research without a prior approval shall be unlawful.

2. Authorisations to conduct biomedical research, with the exception of a clinical trial of a medicinal product, shall be granted by the Lithuanian Bioethics Committee, which shall have the right to delegate these functions to a Regional Biomedical Research Ethics Committee. Where the Regional Biomedical Research Ethics Committee fails to perform these functions properly, its right to grant authorisations may be revoked by a reasoned decision of the Lithuanian Bioethics Committee.

3. Authorisations for a clinical trial of a medicinal product shall be granted by the State Medicines Control Agency under the Ministry of Health subject to approval of the Lithuanian Bioethics Committee or a Regional Biomedical Research Ethics Committee. The procedure for granting authorisations to conduct the clinical trial of the medicinal product shall be laid down by the Ministry of Health.

Version of Article 12 after 1 January 2008:

Article 12. Institutions Granting the Right to Conduct Biomedical Research

1. Biomedical research may be performed in Lithuania only subject to obtaining of an authorisation of the institutions referred to in paragraphs 2 and 3 of this Article.

2. Authorisations to conduct biomedical research, with the exception of a clinical trial of a medicinal product, shall be granted by the Lithuanian Bioethics Committee or a Regional Biomedical Research Ethics Committee. The Regional Biomedical Research Ethics Committee shall grant authorisations to conduct biomedical research where the biomedical research is planned to be conducted at the research centres located solely within the territory attributed to activities of an appropriate Regional Biomedical Research Ethics Committee. An authorisation for a biomedical research planned to be conducted within the territory attributed to activities of more than one Regional Biomedical Research Ethics Committee shall be granted by the Lithuanian Bioethics Committee upon receipt of conclusions of regional biomedical research ethics committees.

3. Clinical trials of a medicinal product may be conducted only being in possession of the approval of the Lithuanian Bioethics Committee to conduct a clinical trial of the medicinal product and the authorisation of the State Medicines Control Agency under the Ministry of Health. The Lithuanian Bioethics Committee shall issue a certificate of the approval to conduct a clinical trial of a medicinal product upon receipt of conclusions of regional biomedical research ethics committees where the clinical trial of the medicinal product is planned to be conducted at the research centres located within the territory attributed to activities of an appropriate Regional Biomedical Research Ethics Committee.

Article 13. Establishment of the Lithuanian Bioethics Committee and Its Sphere of Competence

1. The Lithuanian Bioethics Committee shall be established and its composition and regulations shall be approved by the Ministry of Health. The Lithuanian Bioethics Committee shall be a legal person. Its activities shall be financed from the state budget.

Version of paragraph 2 before 1 January 2008:

2. The Lithuanian Bioethics Committee shall:

1) analyse problems of bioethics and consult state and local government institutions, agencies and organisations on these issues, submit conclusions and proposals relating to the draft laws and other legal acts regulating the problems of bioethics;

2) grant authorisations for biomedical research and undertake ethical review of research as well as control the activities of regional biomedical research ethics committees;

3) annually report to the Ministry of Health about its own activities and make proposals regarding solution of bioethical problems;

4) control whether individual and public health care is in conformity with the requirements of medical ethics and monitor compliance of legal persons with the requirements of bioethics;

5) provide methodological assistance and consult medical ethics commissions of health care establishments and other bioethics institutions on the issues relating to their activities;

6) within the sphere of its competence, represent Lithuania at international organisations;

7) perform other functions specified in its regulations.

Version of paragraph 2 after 1 January 2008:

2. The Lithuanian Bioethics Committee shall:

1) analyse problems of bioethics and consult state and local government institutions, agencies and organisations on the issues of bioethics, submit conclusions and proposals relating to the draft laws and other legal acts regulating these issues;

2) grant authorisations to conduct biomedical research, with the exception of clinical trials of medicinal products, where the biomedical research is planned to be conducted at the research centres located within the territory attributed to activities of more than one Regional Biomedical Research Ethics Committee, and undertake ethical review of this research;

3) issue certificates of the approval to conduct clinical trials of a medicinal product and undertake ethical review of these trials;

4) control the activities of regional biomedical research ethics committees;

5) annually report to the Ministry of Health about its own activities and make proposals regarding solution of bioethical problems;

6) control whether individual and public health care is in conformity with the requirements of bioethics and monitor compliance of legal persons with the requirements of bioethics;-{}-

7) provide methodological assistance and consult medical ethics commissions of health care establishments and other institutions on the issues relating to their activities;

8) within the sphere of its competence, represent Lithuania at international organisations;

9) perform other functions specified in its regulations.

3. The Lithuanian Bioethics Committee shall, in accordance with the procedure laid down by the Ministry of Health, keep a record of biomedical research, accumulate, store and provide information about the research ensuring protection of confidential information, also prepare and approve sample forms of documents.

4. With a view to solving specific problems of bioethics, ad hoc commissions may be formed by the Government.

Version of Article 14 before 1 January 2008:

Article 14. Formation of Regional Biomedical Research Ethics Committees and Their Sphere of Competence

1. Regional biomedical research ethics committees shall be formed in counties with establishments of higher university education and shall be composed proportionally of degree-holding representatives of these establishments, health care specialists and representatives of the public. The quotas of representation in the committees, the number of committee members and composition of the committees, the territory of their jurisdiction shall be established and model regulations of these committees shall be approved by the Lithuanian Bioethics Committee.

2. Regional biomedical research ethics committees shall:

1) grant authorisations, where these functions are delegated to them by the Lithuanian Bioethics Committee;

2) monitor the biomedical research which they have authorised;

3) keep a record of the biomedical research which they have authorised and communicate information from the record to the Lithuanian Bioethics Committee;

4) annually report about their activities to the Lithuanian Bioethics Committee;

5) perform other functions delegated to them by the Lithuanian Bioethics Committee.

Version of Article 14 after 1 January 2008:

Article 14. Formation of Regional Biomedical Research Ethics Committees and Their Sphere of Competence

1. Regional biomedical research ethics committees shall be formed at the universities having in place three-stage medical studies. Funds to finance activities of regional biomedical research ethics committees shall be earmarked in appropriations of the state budget allocated for the Ministry of Health.

2. The procedure for forming and carrying out the activities of regional biomedical research ethics committees as well as for solving the issues assigned to their sphere of competence shall be regulated by regulations of the regional biomedical research ethics committees, which shall be approved by the rector of a university subject to agreement with the Ministry of Health. Territorial boundaries of activities of regional biomedical research ethics committees shall be established by the Ministry of Health.

3. Regional biomedical research ethics committees shall be formed in accordance with the procedure laid down by regulations of the regional biomedical research ethics committees and shall consist of 9 members:

1) two representatives of the biomedical science holding a scientific degree and two representatives of social or humanitarian sciences holding a scientific degree shall be appointed by a university;

2) three health care specialists from the health care establishments functioning in that region and one specialist of the field of social or humanitarian sciences shall be appointed by the Ministry of Health;

3) one member shall be appointed by patients' organisations.

4. The composition of a Regional Biomedical Research Ethics Committee shall be approved by the rector of a university upon agreement with the Ministry of Health. The duration of the term of office of a member of a Regional Biomedical Research Ethics Committee shall be 4 years. A member of a Regional Biomedical Research Ethics Committee may not serve more than two terms of office.

5. A Regional Biomedical Research Ethics Committee shall:

1) grant authorisations to conduct biomedical research, with the exception of clinical trials of medicinal products, where the biomedical research is planned to be

conducted at the research centres located solely within the territory attributed to activities of an appropriate regional biomedical research ethics committee;

2) present conclusions to the Lithuanian Bioethics Committees, where biomedical research is planned to be conducted at the research centres located within the territory attributed to activities of more than one regional biomedical research ethics committee;

3) present conclusions to the Lithuanian Bioethics Committee where clinical trials of a medicinal product are planned to be conducted within the territory attributed to its activities;

4) undertake ethical review of the biomedical research for conduct of which it has granted an authorisation and of the clinical trials of medicinal products for conduct of which it has presented conclusions;

5) keep a record of the authorisations granted;

6) submit reports about its activities to the Lithuanian Bioethics Committee in accordance with the procedure laid down by it.

Version of Article 15 before 1 January 2008:

Article 15. Procedure for Receiving and Considering Applications and Granting Authorisations

1. The sponsor and/or the principal investigator of biomedical research wishing to obtain an authorisation shall submit an application and a list of documents approved by the Ministry of Health to the Lithuanian Bioethics Committee or a Regional Biomedical Research Ethics Committee. The application and documents must be considered and an authorisation must be granted or a reasoned refusal to grant it must be given not later than within 45 calendar days from the registration of the application and all the documents and subject to payment of biomedical research expert examination expenses.

2. The Lithuanian Ethics Committee or a Regional Biomedical Research Ethics Committee shall develop an estimate of expenses of biomedical research expert examination, communicate it to the sponsor and/or the principal investigator of biomedical research who have filed an application and documents, and lay down time limits for payment of the expert examination expenses. When the Lithuanian Bioethics Committee or the Regional Biomedical Research Ethics Committee takes a decision to refuse the granting of an authorisation, the amount paid for the expert examination of biomedical research shall not be refunded to the sponsor and/or the principal investigator of

biomedical research. Where sponsors of research are state higher education establishments, state scientific establishments or state and municipal health care institutions, or where biomedical research is undertaken on medical documents, expert examination shall be conducted free of charge.

3. The procedure for granting authorisations shall be determined by an institution authorised by the Government.

4. The Lithuanian Bioethics Committee or a Regional Biomedical Research Ethics Committee shall have the right to take a decision not to grant an authorisation where the data provided in an application and documents do not conform to the requirements of ethics of biomedical research provided for in this Law, or where the application and documents filed are not properly executed.

Version of Article 15 after 1 January 2008:

Article 15. Procedure for Receiving and Considering Documents and Granting Authorisations

1. The sponsor of biomedical research, its authorised representative and/or the principal investigator wishing to obtain an authorisation shall submit a list of documents approved by the Minister of Health to the Lithuanian Bioethics Committee or a Regional Biomedical Research Ethics Committee. The documents must be considered and an authorisation must be granted or a reasoned refusal to grant the authorisation must be given not later than within 45 calendar days from the receipt of all the properly executed documents.

2. State fee of the established amount shall be paid for expert examination of the documents submitted in order to be granted an authorisation to conduct a biomedical research and for the granting of authorisations.

3. The procedure for granting authorisations to conduct a biomedical research shall be laid down by the Minister of Health.

4. The Lithuanian Bioethics Committee or a Regional Biomedical Research Ethics Committee shall have the right to take a decision not to grant an authorisation to conduct a biomedical research where the data provided in the documents filed do not conform to the requirements of ethics of biomedical research established in this Law, the documents filed are not properly executed, incomplete or misleading information has been provided and the requirement to eliminate these shortcomings has not been complied with.

Version of Article 16 before 1 January 2008:

Article 16. Revocation of an Authorisation

1. The Lithuanian Bioethics Committee or a Regional Biomedical Research Ethics Committee shall have the right to revoke an approval in the event of proving violation of the requirements of ethics of biomedical research provided for in this Law or where so requested by the principal investigator. Evidence of the violation shall be provided by the Lithuanian Bioethics Committee or the Regional Biomedical Research Ethics Committee within the sphere of its competence.

2. The Lithuanian Bioethics Committee or a Regional Biomedical Research Ethics Committee shall, upon taking a decision on the revocation of an authorisation, not later than within 5 calendar days from the taking of the decision, give a written notice to the sponsor and/or the principal investigator of a biomedical research as well as to heads of the health care establishments where the biomedical research is being conducted. The sponsor and/or the principal investigator of biomedical research and heads of the health care establishments where the biomedical research is being conducted must ensure that the biomedical research is terminated without delay.

Version of Article 16 after 1 January 2008:

Article 16. Suspension or Revocation of an Authorisation to Conduct a Biomedical Research

1. The Lithuanian Bioethics Committee or a Regional Biomedical Research Ethics Committee shall have the right to revoke an authorisation to conduct a biomedical research in the event of proving violation of the requirements of ethics of biomedical research provided for in this Law or where so requested by the sponsor of the biomedical research, its authorised representative and/or the principal investigator. Evidence of the violation shall be provided by the Lithuanian Bioethics Committee or the Regional Biomedical Research Ethics Committee within the sphere of its competence.

2. The Lithuanian Bioethics Committee or a Regional Biomedical Research Ethics Committee shall, upon taking a decision on the revocation of an authorisation to conduct a biomedical research, not later than within 5 calendar days from the taking of the decision, give a written notice to the sponsor of the biomedical research, its authorised representative and/or the principal investigator as well as to heads of the health care establishments where the biomedical research is being conducted, who must ensure that the biomedical research is terminated without delay.

3. The Lithuanian Bioethics Committee or a Regional Biomedical Research Ethics Committee shall have the right to suspend an authorisation where there are justified doubts

regarding facts of violation of the requirements of ethics of biomedical research provided for in this Law or where so requested by the sponsor of the biomedical research, its authorised representative and/or the principal investigator. The procedure for suspending authorisations shall be laid down by the Minister of Health.

4. The Lithuanian Bioethics Committee or a Regional Biomedical Research Ethics Committee shall, upon taking a decision on the suspension of an authorisation, not later than within 3 calendar days from the taking of the decision, give a written notice to the sponsor of a biomedical research, its authorised representative and/or the principal investigator as well as to heads of the health care establishments where the biomedical research is being conducted. The sponsor and/or the principal investigator of the biomedical research and the heads of the health care establishments where the biomedical research is being conducted must ensure that the biomedical research is terminated without delay.

Article 17. Procedure for Investigating Complaints

Version of paragraphs 1, 2, 3 and 4 before 1 January 2008:

1. The sponsor of a biomedical research and/or the principal investigator shall have the right to appeal against a Regional Biomedical Research Ethics Committee's decision to refuse the granting of an authorisation or to revoke the authorisation to the Lithuanian Bioethics Committee within 15 calendar days from the receipt of such a decision. The Lithuanian Bioethics Committee must investigate this appeal within 30 calendar days from its receipt.

2. Filing of a complaint shall not suspend the enforcement of a decision on the revocation of an authorisation.

3. Upon examining an appeal by the sponsor of a biomedical research and/or the principal investigator against a Regional Biomedical Research Ethics Committee's decision to refuse the granting of an authorisation or to revoke the authorisation, the Lithuanian Bioethics Committee shall have the right:

1) to uphold the decision of the Regional Biomedical Research Ethics Committee and to dismiss the appeal of the sponsor of the biomedical research and/or the principal investigator;

2) to uphold the appeal of the sponsor and/or the principal investigator of the biomedical research and to grant the authorisation or to take a decision to overrule the decision on the revocation of the authorisation.

4. Where a decision to refuse the granting of an authorisation or to revoke the authorisation is taken by the Lithuanian Bioethics Committee within the sphere of its competence, the sponsor of a biomedical research and/or the principal investigator shall have the right to appeal against such a decision to court within 30 calendar days from the receipt of such a decision in accordance with the procedure laid down by law.

Version of paragraphs 1, 2, 3 and 4 from 1 January 2008:

1. The sponsor of a biomedical research and/or the principal investigator shall have the right to appeal against a Regional Biomedical Research Ethics Committee's decision to refuse the granting of an authorisation, to revoke or suspend the authorisation to the Lithuanian Bioethics Committee within 15 calendar days from the receipt of such a decision. The Lithuanian Bioethics Committee must investigate this appeal within 30 calendar days from its receipt.

2. Filing of an appeal shall not suspend the enforcement of a decision on the revocation or suspension of an authorisation.

3. Upon examining an appeal by the sponsor of a biomedical research and/or the principal investigator against a Regional Biomedical Research Ethics Committee's decision to refuse the granting of an authorisation, to revoke or suspend the authorisation, the Lithuanian Bioethics Committee shall have the right:

1) to uphold the decision of the Regional Biomedical Research Ethics Committee and to dismiss the appeal of the sponsor of the biomedical research and/or the principal investigator;

2) to uphold the appeal of the sponsor and/or the principal investigator of the biomedical research and to grant the authorisation or to take a decision to overrule the decision on the revocation or suspension of the authorisation.

4. Where a decision to refuse the granting of an authorisation, to revoke or suspend the authorisation is taken by the Lithuanian Bioethics Committee within the sphere of its competence, the sponsor of a biomedical research and/or the principal investigator shall have the right to appeal against such a decision to court within 30 calendar days from the receipt of such a decision in accordance with the procedure laid down by law.

5. The subjects or their representatives shall have the right to appeal against actions of the sponsor of research, the principal investigator and other persons involved in the conduct of biomedical research to an institution which has granted an authorisation and to court in accordance with a procedure laid down by laws and other legal acts.

CHAPTER FOUR
FINAL PROVISIONS

Article 18. Liability for Violation of Requirements of Ethics of Biomedical Research

1. Persons in breach of requirements of this Law shall be held liable under law.

2. The fact of conducting a biomedical research without an authorisation or not in compliance with the requirements set forth by this Law and other legal acts, provided the research has not incurred damage to the subject's health, shall be held equivalent to an act of malpractice.

Article 19. Entry into Force of the Law

This Law shall enter into force on 1 January 2001.

Article 20. Proposals to the Government or an Institution Authorised by It, to the State Insurance Supervisory Authority at the Ministry of Finance and to the Ministry of Health

1. By 1 November 2000, the Government or an institution authorised by it shall draw up and approve the Rules for Compulsory Third-Party Insurance of Principal Investigators and Sponsors of Biomedical Research.

2. By 1 October 2000, the State Insurance Supervisory Authority at the Ministry of Finance shall approve the Procedure for Granting Authorisations for Compulsory Third-Party Insurance of Principal Investigators and Sponsors of Biomedical Research.

3. By 1 November 2000, the Government or an institution authorised by it shall draft and approve the legal acts relating to this Law.

I promulgate this Law passed by the Seimas of the Republic of Lithuania.

PRESIDENT OF THE REPUBLIC VALDAS ADAMKUS

Version of the Annex before 1 January 2008:

Annex to
Republic of Lithuania
Law No VIII-1679
of 11 May 2000

IMPLEMENTED EU LEGAL ACT

Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

Version of the Annex after 1 January 2008:

Annex to
Republic of Lithuania
Law on Ethics
of Biomedical Research

LEGAL ACTS OF THE EUROPEAN UNION IMPLEMENTED BY THIS LAW

Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use (OJ 2004 Special edition, Chapter 13, Volume 26, p. 299).